In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-0862V

ARTHUR FRENCH,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 27, 2023

Michael G. McLaren, Black McLaren Jones Ryland & Griffee, P.C., Memphis, TN, for Petitioner.

Tyler King, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW[1]

On July 15, 2020, Arthur French filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that he suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table Injury, after receiving an influenza ("flu") vaccine on October 26, 2019. Petition at 1, ¶¶ 2, 13.

[1] Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons set forth below, a preponderance of the evidence reveals a current condition that would potentially explain Petitioner's symptoms – meaning the Table SIRVA claim must be dismissed. A causation-in-fact or significant aggravation versions of the claim could succeed, however, although it remains to be determined whether the six months "severity" requirement applicable to all Program claims can be satisfied.

I. Relevant Procedural History

During the five months following the filing of his petition in July 2020, Mr. French filed the affidavit and medical records required under the Vaccine Act. Exhibits 1-13, ECF Nos. 6, 8, 11, 13, 15; *see* Section 11(c). On February 2, 2021, the case was activated and assigned to the Special Processing Unit. ECF No. 17.

More than a year later, on May 3, 2022, Respondent filed his Rule 4(c) Report, opposing compensation in this case. ECF 36. Respondent questioned whether severity had been established, noting the improvement Petitioner obtained during 24 physical therapy ("PT") sessions from late December 2019 through early March 2020, as well as the lack of any mention of ongoing shoulder symptoms during the eight-month period thereafter, despite attending multiple orthopedic and PT visits for unrelated conditions. *Id.* at 3-6, 9; *see* Section 11(c)(1)(D)(i). Additionally, Respondent maintained that the record suggested an alternative cause for his injury that would preclude a SIRVA finding. *Id.* at 7-9; *see* 42 C.F.R. § 100.3(c)(10)(iv) (requiring the lack of a potential alternative cause).

On June 7, 2022, I issued an order instructing Petitioner to provide additional evidence to satisfy the statutory six-month requirement or otherwise show cause why his claim should not be dismissed. Order to Show Cause at 5-6, ECF No. 37. In response, Petitioner filed new or corrected medical records,[3] photographs of devices used to combat his shoulder pain,[4] a supplemental affidavit, an expert report[5] and medical literature cited

[3] Petitioner has filed corrected PT records which show the lower back pain he previously experienced and attended PT for occurred in early 2018, not during the summer of 2020 as prior records showed. *Compare* Exhibit 17 (correct records) *with* Exhibit 6 at 6-10 (incorrect records from another individual).

[4] Petitioner provided photographs of an Icy Hot electronic stimulator and "hydroculator." Exhibits 18-19, ECF No. 39. Although there is a version of the Icy Hot electronic stimulator designed specifically for the knee and shoulder, Petitioner is using the version for back and hip pain. https://www.walmart.com/ip/Icy-Hot-Smart-Relief-Back-and-Hip-Pain-Therapy/35880065 (last visited on Sept. 25, 2023) (version for back and hip pain) *with* https://www.walmart.com/ip/Icy-Hot-Smart-Relief-Knee-and-Shoulder-TENS-Therapy/46521717?from=/search (last visited on Sept. 25, 2023) (version for knee and shoulder pain).

[5] I note that Petitioner did not seek approval before retaining his orthopedic expert in this case. As a routine matter, I include a warning not to retain a medical expert, life care planner, or other expert in SPU cases without my prior approval as the involved cost may not be found to be reasonable. The SPU initial order

in the report and written response. Exhibits 17-40, ECF Nos. 38-40, 42-43; Petitioner Brief to Order to Show Cause ("Brief"), ECF No. 44.

In November and December 2022, Respondent filed a responsive expert report, curriculum vitae ("CV"), and cited medical literature. Exhibits A-B, ECF Nos. 46-47. Failing to mention the Vaccine Act's severity requirement (despite my having highlighted it as a matter warranting development or input), Respondent's expert addressed only the requirements for a Table SIRVA and causation-in-fact claim. *See* Exhibit A.

II. Relevant Factual History

Approximately ten years prior to the October 26, 2019 vaccination, Petitioner purportedly underwent surgery to repair a left shoulder rotator cuff tear. Petition at ¶ 3; Exhibit 1 at ¶ 4. Due to the provider's practice of destroying medical records after ten years, however, records specific to this treatment event are unavailable. Exhibit 16 at 2. A retired New York detective and 80 years old when vaccinated, Petitioner also suffered from diabetes, chronic lower back pain, requiring a stenosis debridement in November 2018, and bilateral knee pain. Exhibit 6 at 6; Exhibits 8-9, 17; Exhibit 20 at 6.

On October 26, 2019, Petitioner received a flu vaccine intramuscularly in his left deltoid. Exhibit 11 at 3. Approximately three weeks later, on November 15, 2019, he visited his primary care provider ("PCP") for preventive care, left shoulder pain, and urinary frequency. Exhibit 7 at 4. Noting that he had received a flu vaccine one month earlier, he reported that "[a]bout 24-48 hours after the shot, [he] began to feel muscular pain alongside radiating pain down to the mid bicep with abrupt, upward movement." *Id.* Petitioner was instructed to undergo an MRI which revealed sequelae of his prior left rotator cuff repair with a "decrease in marrow edema and mild fluid along the screw compared to [a] prior MRI,"[6] no definitive rotator cuff tear, and "very mild edema in the subcutaneous tissues lateral to [his] left shoulder." Exhibit 5 at 11.

When Petitioner returned for treatment on December 17, 2019, he reported that he "developed pain 2 days after" vaccination, and that "[w]hile he was playing golf he felt soreness in his upper shoulder and [it] has since not gone away." Exhibit 4 at 2. He added that he was told that he might have a SIRVA injury. According to this record, Petitioner had a "past surgical history [of both] *left* and *right* shoulder cuff repairs." *Id.* (emphasis

containing this admonishment was issued in this case on February 8, 2012. SPU Initial Order at 1, ECF No. 18.

[6] According to this medical record, Petitioner underwent a prior left shoulder MRI on May 19, 2019. Exhibit 5 at 10.

added). He was assessed as having "left shoulder post injection edema, rotator cuff and biceps tendinitis without tear," prescribed PT, told he could continue to play golf, and instructed to "follow up in 6-8 weeks for progression [to] consider [a] cortisone injection if worsening or not improved." *Id.*

From late December 2019 through mid-March 2020, Petitioner attended 24 PT sessions. Exhibit 6 at 15-79. At the first session, Petitioner reported dull and aching left shoulder pain since receiving the flu shot in early October 2019. *Id.* at 78, 80. By his last session on March 10, 2020[7] - four and one-half months post-vaccination - he reported "less severe and frequent but 'annoying,' 3/10 [pain] at worst." *Id.* at 15. Describing incidents of "2 twinges in [his] shoulder yesterday" while raking leaves for 20 minutes before feeling pain and a sharp, stabbing pain when reaching behind his back or into the dishwasher, Petitioner stated that "he is continuing to work on posture and performing HEP as prescribed." During his assessment, Petitioner was noted to be pain free with internal and external rotation up to 90 degrees. *Id.* at 16. Additional PT was recommended. *Id.*

Petitioner thereafter sought medical treatment from his PCP twice in April 2020, for a tick bite and monitoring of his high blood pressure and diabetes. Exhibit 7 at 15-19; Exhibit 12 at 4-7 (respectively). During the subsequent months of July through September 2020, he was seen by the orthopedist on five occasions for treatment of bilateral knee pain. Exhibit 15 at 14-24. There is no mention of left shoulder pain in any of these records. *Id.*

On November 20, 2020 (now more than eight months after his last PT session), Petitioner attended PT for "L side shoulder blade and neck pain with reaching forward or [prolonged] driving." Exhibit 13 at 14. He attended a total of four PT sessions in November and December 2020. *Id.* at 4-19. Although the location of Petitioner's pain differed slightly, occurring in his shoulder blade and left side of his neck as well as the top of his shoulder, the onset date was the same as previously identified – October 1, 2019. *Compare,* e.g., Exhibit 13 at 10 *with* Exhibit 6 at 64. And these later PT sessions were consecutively numbered 25 - 28. Exhibit 13 at 12, 10, 8, 6 (in consecutive order).

In March 2021, Petitioner visited his orthopedist for a sprain of the metacarpophalangeal joint of his right thumb, suffered when opening a bottle. Exhibit 15 at 12-13. The orthopedist also examined Petitioner's spine and knees, recommending future injections for the osteoarthritis in his knees. *Id.* at 13. In April 2021, Petitioner

[7] Petitioner may have attended one more session on March 13, 2020, as there is an exercise log for a visit on that date. Exhibit 6 at 11. However, there is no further record for a visit on that date, and no visit number is assigned for a March 13 visit.

underwent a series of injections in his knees. *Id.* at 2-11, 16-26. There is no mention of left shoulder pain in these more recent medical records. And no updated medical records have been filed.

III. Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). According to the most recent version of the Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The specific criteria establishing a SIRVA are as follows:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (additional requirements set forth in the *Qualifications and Aids to Interpretations* ("QAI")). If a petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Hum. Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a pre-existing injury, petitioners must establish three additional factors. See *Loving v. Sec'y of Health & Hum. Servs*., 86 Fed. Cl. 135, 144 (Fed. Cl. 2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three Althen factors for off table injury claims to create a six-part test for off-Table aggravation claims). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) whether the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *Loving*, 86 Fed. Cl. at 144.

Whether proceeding under a Table, causation-in-fact, or significant aggravation claim, a petitioner must satisfy the other requirements of Section 11(c) regarding the vaccination received, the duration and severity of her injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D). Finding a petitioner is entitled to compensation must not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner's medical issues. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

IV. The Parties' Experts

On August 3, 2022, Petitioner filed an expert report from Uma Srikumaran, M.D., an Associate Professor of Orthopaedic Surgery at Johns Hopkins School of Medicine since 2011. His medical training included a Fellowship in Shoulder Surgery at Harvard University. Estimating that he treats approximately 2,500 to 3,000 patients with shoulder issues each year, Dr. Srikumaran "ha[s] treated approximately 10-12 patients with shoulder dysfunction after vaccination in the past 5 years." *Id.*

Respondent's expert, Paul J. Cagle, M.D., is an Associate Professor of Orthopaedic Surgery and Associate Residency Program Director at the Department of Orthopedics at Icahn School of Medicine at Mount Sinai in New York City. Exhibit A at 1; Exhibit B at1. His medical training included a Shoulder and Elbow Fellowship at Mount Sinai Hospital. Exhibit B at 1. He has earned a patent, several awards of grand funding, and numerous honors. *Id.* at 2-3.

Both experts are board certified by the American Board of Orthopaedic Surgery and have published numerous articles related to shoulder surgery. Exhibit 23 at 1; Exhibit B at 1, 3-10. Additionally, Dr. Srikumaran has published two articles related to SIRVA injuries. Exhibit 23 at 1. Both Dr. Srikumaran and Dr. Cagle are highly qualified to opine in this case.

V. Table SIRVA Claim

Dr. Cagle opines that Petitioner has failed to satisfy the first, third, and fourth QAI criteria for a Table SIRVA (Exhibit A at 3). *See* 42 C.F.R. § 100.3(c)(10)(i), (iii)-(iv). He maintains that Petitioner's prior left shoulder pain and rotator cuff repair prevents Petitioner from satisfying both the first and fourth QAI criteria, as it constitutes both evidence of prior dysfunction as well as a current condition which would explain the symptoms Petitioner experienced. Exhibit A at 3; *see* 42 C.F.R. § 100.3(c)(10)(i), (iv). Regarding the requirement that Petitioner's pain and limited range of motion ("ROM") be limited to the injured shoulder, Dr. Cagle maintains there is insufficient evidence to establish Petitioner suffered *any* limitation in ROM because the mild percentage he exhibited could have been resulted from his earlier rotator cuff repair, and thus may have been present prior to vaccination. Exhibit A at 3-4; *see* 42 C.F.R. § 100.3(c)(10)(iii).

As I have previously stated, "it is not readily apparent that the QAI to establish a Table SIRVA injury requires that a petitioner establish that he suffered limited or reduced range of motion." *Dawson v. Sec'y of Health & Hum. Servs.,* No. 19-0278V, 2021 WL 5774655, at *2-3 (Fed. Cl. Spec. Mstr. Nov. 4, 2021). However, I need not resolve that ambiguity in the Table definition here, since Petitioner exhibited a definite, albeit mild, limitation in his ROM. And Dr. Cagle's assertion that this slight limitation may have been present prior to vaccination is speculative and not supported by the record in this case.

Regarding the first and fourth QAI criteria, however, Respondent's objections are better substantiated. Dr. Srikumaran maintains that Petitioner's history of a prior rotator cuff repair does not prevent him from satisfying the first criteria (that he had no history of pain, inflammation, or dysfunction of the left shoulder that would explain his current symptoms and findings post-vaccination) because "[P]etitioner's symptoms had been dormant and stable" since the rotator cuff repair. Exhibit 23 at 4. Dr. Cagle counters that Dr. Srikumaran's argument alters the meaning of the first criterion, and that his use of the term "dormant" implies that the repair could have produced Petitioner's post-vaccination symptoms. Exhibit A at 3.

Discussing the differences between a shoulder condition which resolves with conservative treatment and one that requires a surgical repair, Dr. Cagle opines that "[i]t is highly plausible that a shoulder with a rotator cuff tear that was severe enough to require surgery could become painful again sometime in the future." *Id.* He insists a prior condition such as Petitioner's rotator cuff repair constitutes "a viable explanation for [Petitioner's] subsequent shoulder pain." *Id.* at 5.

A petitioner will fail to satisfy the first and fourth QAI criteria if there is preponderant evidence of a prior or current condition that *would* explain the petitioner's current symptoms. *See* 42 C.F.R. § 100.3(c)(10)(i), (iv). The condition or abnormality must qualify as an explanation for the symptoms a petitioner is experiencing, but need not be a better or more likely explanation. *Durham v. Sec'y of Health & Hum Servs.,* No. 17-1899V, 2023 WL 3196229, at *13-14 (Fed. Cl. Spec. Mstr. Apr. 7, 2023). In effect, and although the same preponderant evidentiary burden applies to this QAI as with all others, this Table element does not impose on Respondent the obligation to prove an "alternative cause" for the injury, but instead merely that the record contains sufficient evidence of a competing explanation to "muddy" a finding that vaccine administration was the cause.[8]

Both parties and their respective experts acknowledge Petitioner's prior rotator cuff repair, and that it caused sequela clearly visible on the MRI performed in November 2019, including a decrease in marrow edema and mild fluid along the screw. *See* Exhibit 7 at 13-14 (the MRI results). The record does not support Petitioner's contention that he has satisfied the fourth QAI criteria, and therefore he cannot establish a Table claim.

VI. Remaining Issues to be Addressed

Although I am dismissing Petitioner's Table claim, he *could* prevail under a causation-in-fact and/or significant aggravation claim. Approximately three weeks post-vaccination, the results of the November 20, 2019 MRI revealed "mild fluid along the screw . . . [and] [v]ery mild edema in the subcutaneous tissues lateral to [the] left shoulder." Exhibit 7 at 13-14. And, after viewing the results of the MRI, Petitioner's PCP diagnosed him with left shoulder post injection edema. *See* Exhibit 4 at 2. The vaccination could thus have caused some kind of SIRVA-like injury, whether new or by worsening Petitioner's existing prior injury.

[8] Of course, claims that are styled as a SIRVA Table claim but which "fall out" may still remain viable as a causation claim – and in such circumstances the usual considerations applicable to "factor unrelated" alternative causes, and the shifted burden considerations, will come into play. For present purposes, what matters is that this Table element expressly requires the *petitioner* to show no other "condition or abnormality."

If Petitioner wishes to continue with his claim, however, some further record substantiation is required. In particular, he needs to provide additional evidence, such as the results of and reason for the May 2019 MRI referenced in the report from the November 2019 MRI, or an explanation for that reference if a left shoulder MRI was not performed in May 2019, for the time approximately five months prior to vaccination.[9] Additional evidence is also required for a finding that the severity requirement of six months post-onset symptoms has been met.

In response to my Order, Petitioner has provided more credible arguments regarding the latter. Although he sought treatment for other conditions during the eight-month gap from March through November 2020, these visits (which occurred during the height of the COVID pandemic) were for specific unrelated conditions which required more immediate treatment. *See* Exhibit 7 at 15-19; Exhibit 12 at 4-7; Exhibit 15 at 14-24; Brief at 3-5; Exhibit 23 at 4-6 (expert report); Exhibit 17 at 10, 13-17 (second affidavit). And the records from PT sessions from this time which undercut Petitioner's claim of continued symptoms have been proven to be for another individual, and thus were erroneously included in Petitioner's records. *See* Exhibit 6 at 6-10 (records from PT sessions in June 2020 for another individual). Furthermore, Dr. Srikumaran provided an expert opinion indicating Petitioner's later reports of left sided neck and shoulder blade pain can be attributed to the "nature progression that SIRVA injuries can take." Exhibit 23 at 5.

Respondent's expert, by contrast, failed to address the issue of severity. *See* Exhibit A (expert report). Because this omission was likely an oversight, I will allow Respondent the opportunity to provide his arguments regarding severity. (If the omission was intentional because Respondent and his expert believe Petitioner has satisfied this requirement, Respondent may indicate that fact in a status report).

Finally, and although the parties have already had ample opportunity to settle the claim, I urge them to make one final effort. Even if Petitioner is found to be entitled to compensation, I do not expect the amount awarded would be substantial. It seems unlikely the Petitioner (who was retired) would have a claim for lost wages, and treatment here was not extensive. In addition, Petitioner's pain was mild - often occurring only with certain movements - and his limited ROM was slight. Any pain and suffering award would likely be well below the six-figure threshold. The case will, however, be transferred if the parties cannot succeed in settling the matter before the middle point of the fall 2023.

[9] *See* Exhibit 7 at 13 (indicating the results of the left shoulder MRI performed on November 15, 2019 were compared to the result of a prior MRI performed on May 19, 2019).

Conclusion

The record contains preponderant evidence showing Petitioner suffered from a prior and current condition which would explain his left shoulder symptoms. Accordingly, his Table SIRVA claim is DISMISSED.

Before I determine whether Petitioner has satisfied the Vaccine Act's six-month severity requirement, evaluate the merits of any off-Table causation or significant aggravation claim, or determine that the case should be transferred out of SPU, I will allow the parties the opportunity to engage in settlement discussions.

That parties are hereby ORDERED to file a joint status report indicating whether they believe an informal resolution can be reached and providing their preferred next step(s) in the case by Friday, November 14, 2023.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master